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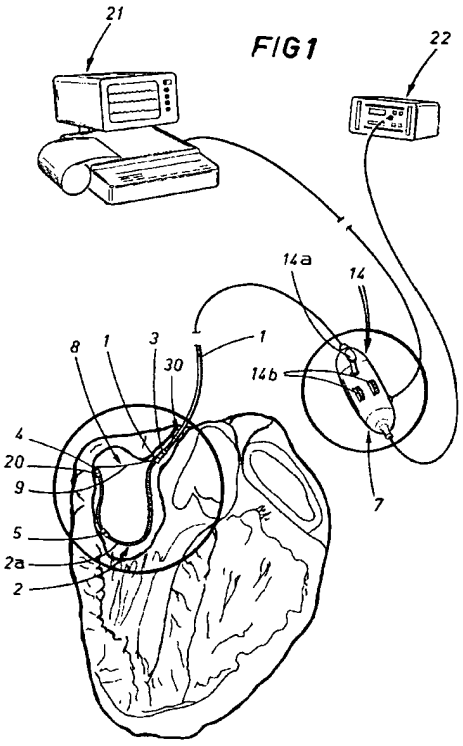
(54) An electrode catheter for mapping and operating on cardiac cavities.

(57) An electrode catheter designed for intravenous insertion into a cavity of the heart comprises a tubular sheath (1) encasing a first spiral wound wire (2) of conductive biocompatible material, which affords an insulated operative portion (2a) exposed from the sheath (1) and capped distally by a domed ring (4), and a mapping electrode (5) of conductive biocompatible material for sensing the electrical activity in the cardiac muscle, carried coaxially by the first spiral wound wire (2) and capable of movement along the operative portion (2a) transmitted by means of a second spiral wound wire (6) extending coaxially through the first (2) and connected to an external control handset (7). The operative portion (2a) of the first wire (2) is arched by means of a tension wire (9) designed to establish a restraint between the domed ring (4) and the distal end of the sheath (1), of which the length can be increased or reduced to alter the radius of the arched profile as expedient for the shape of the cavity explored.

FIG 1



EP 0 609 182 A1

The present invention relates to an electrode catheter by means of which to map and if necessary perform an ablation internally of a cardiac cavity, in particular the right and left atria, the mitral valve and the ventricle.

Among the aims currently being pursued in medical and surgical technology, assisted not least by an increasingly widespread miniaturization and greater precision of the equipment available, there is a move toward the creation of a family of instruments which can be used, on the one hand, to monitor all such electrical activities of the cardiac muscle as will tend to widen the scope for the prevention of heart trouble, and on the other, simultaneously and where necessary, to perform a surgical operation.

Whilst the measurement of electrical activity in the cardiac muscle is central to a full exploration of the cardiac cavities, the process of effecting the measurement is made difficult by the particular anatomy of the organ; the internal characteristics of the heart do not respond to a standard pattern, in effect, but vary from patient to patient.

As regards the treatment of heart diseases likely to generate situations of serious trouble, to the point of triggering fibrillation, the following options are available:

- open heart surgery, performed to remove the zone affected by the trouble: an operation accompanied by risks and consequences well known to a person skilled in the art;
- installation of a defibrillator device, which will detect the trouble at the moment of onset and counteract the effect by producing a high voltage electrical discharge through a catheter implanted permanently in the patient: a solution involving high risk to the patient (insofar as the discharge can occur at any moment and without warning) and considerable cost:
- non-invasive sensing of the trouble zone by means of a probe, with immediate ablation of the affected muscle fibres: a more recently introduced technique which involves the least risk and disturbance for the patient.

At the time of filing the present application, the prior art embraces few instruments of diagnosis or surgery that can be utilized non-invasively in the manner referred to above, or at least to carry out an accurate measurement and a swift verification of the electric activity in the cardiac muscle. One such instrument consists in a unipolar or multipole electrode catheter insertable into the myocardium through a vein, of which the inserted end affords a sensor (or indeed a plurality of sensors in the case of a multipole type) connected electrically to external monitoring m ans, which can be manoeuvred around internally of the cardiac zone in question.

The catheter consists for practical purposes in a pair of parallel control wires united at one end by the terminal sensor and linked at the remaining or non-operativ end to a control device functioning in the manner of a tiller, which when rotated one way or the other will impinge on a corresponding wire, causing the end of the catheter that carries the sensor or sensors to assume an arched profile; the arched portion can then be revolved through a plurality of positions in space by rotating the catheter about its own axis.

In this way, the surgeon can effectively "copy" the profile of the explored cardiac zone by sampling the electrical activity of the muscle discretely, with the aid of auxiliary computerized monitoring equipment which is programmed to make allowance for the dimensions of the electrode catheter, and in particular the distance of the operative portion from the point at which the catheter enters the cardiac cavity (referred to generally as the "zero" reference), and to calculate and map the copied profile by interpolation of the discontinuously monitored input data.

In the event that the exploration should reveal an irregular electrical activity in certain cardiac tissues, the selfsame device can be used by the surgeon to carry out an ablation in loco, that is, to burn away a small bundle of muscle fibres and thus eliminate the site of the irregular activity, by means of the terminal sensor utilized previously in the mapping operation; this would be effected with the aid, for example, of a radio frequency device.

The mapping device briefly outlined above betrays considerable drawbacks, however: the configuration of the catheter and the structuring of the wires and the relative control system combine to limit the radius of curvature available to the operative portion and thus allow no more than an approximate scanning and measurement of the cardiac cavities; also, the operations of calibrating and resetting the instruments are lengthy (even for very small dimensions) not least by reason of the fact that the reset (i.e. initial recognition of the "zero" reference) must be effected with a separate probe catheter which, once the position internally of the cardiac cavity has been located, will be removed to allow space for insertion of the mapping catheter, which in its turn must be positioned initially in relation to the zero reference in order to ensure that the zone is mapped correctly. Such a procedure obviously dictates a marked extension of the times required simply to perform the various steps, and this could be damaging to the patient ultimately, especially in cases where there may be the need to perform an ablation at sites registering irregular electrical activity.

In a further solution, disclosed in EP 499 491, the operative portion of th catheter incorporates a plurality of sensing poles or el ctrodes uniformly distributed along a probe capable of expanding axially in such a way as to allow of altering the distance between the single electrodes, from which corresponding signals are returned to an external controller; the

multipole version of this device is somewhat complex, and in any event the catheter can not asily be adapted and matched to the different shapes of the cavities explored. As a result, there are difficulties in effecting the measurement part of the mapping operation, which remains lengthy and imprecise.

Accordingly, the object of the present invention is to overcome the drawbacks mentioned previously, by providing a cardiac mapping and ablation catheter of constructionally simple architecture, affording a wide range of configurations and thus adaptable to any cardiac cavity, while ensuring precision and completeness in every movement and in control over the configurations selected; such a catheter will allow a total and continuous scan of the zones of electrical activity and guarantee especially short operating times whether in monitoring or performing an ablation of cardiac tissue, and can be offered in a disposable format at relatively low cost.

The stated object is fully realized in an electrode catheter as characterized in the appended claims.

The invention will now be described in detail, by way of example, with the aid of the accompanying drawings, in which:

- fig 1 illustrates the mapping electrode catheter according to the invention in a perspective view, connected to monitoring instruments, with certain details enlarged;
- fig 2 and fig 3 are enlarged side elevations of the operative portion of the catheter according to the invention, in which certain parts are seen in section and others cut away;
- fig 4 illustrates certain of the configurations that can be assumed by the operative portion of the electrode catheter of figs 1 to 3, in a series of side elevations;
- figs 5, 6 and 7 are schematic sectional views of the heart, each showing the electrode catheter in a possible operating configuration inside one of the cardiac cavities.

With reference to the accompanying drawings, the cardiac mapping electrode catheter to which the invention relates is a disposable device, of which the principal elements include: a tubular sheath 1, a first spiral wound wire 2, a medial electrode 5, and means 8 by which to alter the configuration of the first spiral wound wire 2.

More in detail (see figs 1, 2 and 3), the sheath 1 affords a casing for the first wire 2, which is fashioned in a conductive biocompatible material and insulated electrically at least on the surface (for example, by the application of an atomized carbon coating), and insertable intravenously into a cavity of the cardiac muscle (atrium, ventricle or mitral valve). The tubular sheath 1 is encircled by a first ring 3 located near to the distal end, from which the first wire 2 extends into an exposed operative portion 2a terminating at and capped off by a second ring 4. The extremity of the operative portion 2a is fitted over a cylindrical shank 4c afforded by th second ring 4 and held securely in place by a fourth ring 20, positioned over the wire and crimped.

The medial electrode 5, which consists in a sensor embodied in electrically conductive biocompatible material serving to measure the electrical activity of the cardiac muscle, is positioned coaxially to the first wire 2 and capable of movement along the exposed operative portion 2a produced by relative means consisting in a second spiral wound wire 6 disposed coaxially to the first wire 2 and secured at the proximal end to control means 7 operated from outside the body of the patient (such means will be conventional in embodiment, consisting for example in stepping motors controlled by means of a joystick, and therefore are not shown in detail).

The geometry of the medial electrode or sensor 5 can be selected to suit the particular anatomical requirements encountered: in fig 2 for example, the electrode 5 is illustrated in section (bold lines) as a cylindrical element exhibiting flat external surfaces, and shown in phantom line with spherical external surfaces.

More exactly, the second spiral wound wire 6 (see fig 2) is passed slidably and coaxially through the first wire 2 and rigidly associated with a worm 12 rigidly anchored in its turn (by microwelding, for example) to the internal surface of the electrode 5 and coupled helically with the first wire 2 such that a rotation of the second wire 6 left or right will also cause the medial electrode 5 to rotate, and in consequence translate along the operative portion 2a of the first wire 2 in the corresponding direction. The second wire 6 is also accommodated internally of a second sheath 6g and furnished at the distal end with an ogival head 13 of spherical profile seated coaxially in the bore of the distal extremity and positioned at a distance from the electrode 5 such as will afford a certain measure of flexibility and allow the second wire 6 to slide freely through the first wire 2 whenever a change in the configuration of the operative portion 2a is produced by activating the means 8 aforementioned.

Such means 8 by which to alter the configuration of the operative portion 2a of the first spiral wound wire 2 are designed to operate between the second ring 4 and the distal end of the first sheath 1, and consist in a flexible tension wire 9 (also of biocompatible material) capable of axial movement in relation to the first wire 2 and establishing a chord, subtended by the operative portion 2a, of which the length can be varied according to the morphology of the cardiac cavity, in such a manner that a rotation of the first spiral wound wir 2 through 360° about its own axis will result in the operative portion 2a engaging in full contact with the ntire surface of the cavity. As discernible from fig 3, the flexible tension wire 9 is anchored

at one end, internally of th s cond ring 4, by means of a cylindrical retaining element 10 lodged within a cylindrical cavity afforded by the body of the second ring 4; the second ring also presents a domed cap with a through hole 11 affording an exit passage to the wire 9. As illustrated in fig 2, the tension wire 9 is taken up through the distal end of the first sheath 1 substantially parallel to the first spiral wound wire 2, stabilized radially and protected by a third spiral wound wire denoted 23 (while obviously retaining freedom of longitudinal movement), and connected by the remaining end to the external control means 7 mentioned previously; thus, the control means 7 can be operated to modify the configuration of the first wire 2 and at the same time to establish a chordal restraint, once the desired configuration is obtained, such as will favour continuous contact of the medial electrode 5 with the walls of the cardiac cavity explored.

With the arrangement thus described, whereby the first spiral wound wire 2 and the tension wire 9 are harnessed to the sheath 1 and encircled by the first ring 3 for increased stability, the sheath 1, the first wire 2, the second ring 4 and the tension wire 9 are connected to the control means 7 as a composite assembly and rotatable as one.

For particular medical and technical requirements such as when analyzing the atrial signal, by way of example, the second ring 4 at the free end of the operative portion 2a might be rendered electrically active, likewise the first ring 3 at the end of the sheath 1, if appropriate, in such a way as to equip the catheter with a distal electrode and a proximal electrode; in this instance the electrical signal from the distal electrode 3 can be returned by way of a further conductor 3c as illustrated in fig 3.

Naturally, the sensing electrode 5 might also be used to effect an ablation of cardiac tissue, in the event that an anomalous electrical activity is detected, by means of a connection to conventional radio frequency appliances (as shown in fig 1), or by equipping the catheter with optical fibres and using laser technology.

The manner of utilizing the electrode catheter according to the invention will now be described.

It is the nature of the particular cardiac cavity to be explored that will dictate the selection of the catheter, as regards the diametral dimensions and the size of the exposed operative portion 2a; having made the appropriate selection, the surgeon inserts the catheter through a pulmonary vein and into the myocardium (see figs 1, 4, 5, 6 and 7), then proceeds with the assistance of radioscopic media to initialize the monitoring instruments and the catheter utilizing the proximal and distal electrodes 3 and 4, and if necessary the medial electrode 5 also. This done, the non-active portion of the catheter is secured internally of the vein (by means of conventional technologies r presented schematically by the element denoted 30 in fig 1), whereupon the surgeon can b gin mapping the cardiac cavity under scrutiny, using a control handset 14 to advance or retract the flexible tension wire 9 (see arrow F, fig 3) and thereby alter the axial configuration of the operative portion 2a in such a way as to bring the surface of the first spiral wound wire 2, and therefore the medial electrode 5, progressively into contact with the entire band of cardiac muscle that lies adjacent to the operative portion 2a; being offered in contact to the cardiac muscle fibres, in the case of very small cavities in particular, the tension wire 9 functions as a chordal restraint by which the first spiral wound wire 2 is effectively forced into the cavity and kept stably in position throughout the subsequent exploration performed via the medial electrode, or sensor 5. In the examples illustrated, fig 1 shows the mapping of the left atrium, fig 5 the mapping of the left ventricle, and figs 6 and 7 the mapping of the mitral valve muscle fibres with the heart in diastole and systole respectively.

As already intimated, the control means 7 allowing manipulation of the first wire 2, tension wire 9 and second wire 6 are incorporated into a single externally operated handset 14, indicated in fig 1, which also provides the means by which the catheter is connected up to the electronic and informatic monitoring instruments 21 and 22, also visible in fig 1. The control element proper might consist in a joystick 14a, of which the movement will activate a small electric motor keyed to the second spiral wound wire 6 and designed to respond by effecting one full revolution; the flexible tension wire 9 and the means 30 for securing the catheter can be operated by means of a pair of levers 14b.

Once the operative portion 2a is in the required configuration, the surgeon utilizes the handset 14 to rotate the second wire 6 left or right and thus occasion an extending or retracting movement in relation to the first wire 2 (see arrow F1, fig 2) such as will alter the position of the electrode 5 and permit of scanning the electrical activity in the zone against which the operative portion 2a of the catheter is brought to bear. Thereafter, still using the handset 14, the securing means 30 can be manipulated to rotate the assembly of the sheath 1, first wire 2, second ring 4 and tension wire 9 through a given angle (arrow F2, figs 5, 6 and 7), while continuing to maintain uniform contact with the endocardium, and thus obtain a full 3600 scan of the cardiac cavity; in practice, the surgeon can either rotate the operative portion 2a of the first wire 2 in the cavity with the medial electrode 5 in a fixed position, or produce the selfsame rotation whil causing the electrode 5 to translate along the wire 2 at one and th same time.

Clearly, in the event that the exploration should reveal any electrical activity of irregular nature within the cavity, the surgeon can operate without delay util-

izing the radio frequency apparatus, the technique being simply to heat the medial electrode and thus allow of "scorching" the muscular tissues that may be at risk or malfunctioning in any way.

Several significant advantages are afforded by the electrode catheter described and illustrated: the notable speed with which the catheter is connected and positioned internally of the cardiac cavity to be explored; a practically unlimited anatomical adaptability, thanks to the numerous configurations which can be assumed by the operative portion of the spiral wound wires; precision and completeness in the operation of scanning electrical activity, given the ability of the first wire to rotate 360° while maintaining the selected anatomical profile.

It will be noted, moreover, that a probe rotatable through 360° can be employed not only to produce a complete scan of electrical activity but also to effect a measurement of the ring encircling the mitral valve, a procedure difficult to accomplish with previous solutions.

Claims

1) An electrode catheter for mapping and operating on cardiac cavities, in particular the right and left atria, the mitral valve and the ventricle, composed of at least one tubular sheath (1) fashioned from a biocompatible material, and at least one spiral wound wire of electrically conductive material accommodated internally of the tubular sheath and insertable intravenously into the cavities of the cardiac muscle, characterized,
in that it comprises:

- a first spiral wound wire (2) of biocompatible material accommodated internally of the tubular sheath (1) and affording an electrically insulated operative portion (2a) exposed from the sheath;
- a first ring (3) occupying a fixed position near to the distal end of the sheath (1);
- a second ring (4), permanently associated with and capping the distal extremity of the operative portion (2a);
- a third ring (5) fashioned from an electrically conductive and biocompatible material, constituting a medial electrode and acting as a sensor by means of which to measure electrical cardiac activity, associated coaxially with the first spiral wound wire (2) and capable of translatory movement along the operative portion (2a) through the agency of means consisting in a second spiral wound wire (6), disposed coaxially to the first wire (2), of which one end is permanently associated with the ring (5) and the remaining end is connected to externally operated means (7) for inducing and controlling the translatory movement;
- means (8) by which to alter the configuration of the operativ portion (2a) of the first wire (2), embodied as a flexible tension element (9) interconnecting the second ring (4) and the distal end of the sheath (1) and invested with axial movement in relation to the first wire so as to increase or reduce the length of the interconnection according to the morphology of the cavity, in such a manner that the operative portion (2a) can be brought into contact with the entire surface of the cavity by rotating the first wire (2) through 360°.

2) An electrode catheter as in claim 1, wherein the means (8) by which to alter the configuration of the operative portion (2a) of the first spiral wound wire (2) consist in a flexible tension wire (9) anchored at one end by means of a cylindrical retaining element (10) lodged within a cylindrical cavity afforded by the second ring (4), passing through a hole (11) afforded by a domed cap forming an integral part of the second ring (4), directed back into and along the sheath (1) substantially parallel with the first spiral wound wire (2) and accommodated within a third spiral wound wire (23) affording protection and stability in the radial direction, and connected by the remaining end to the externally operated control means (7).

3) An electrode catheter as in claim 1, wherein the first spiral wound wire (2) is anchored permanently to the tubular sheath (1), and the sheath (1), the first wire (2), the second ring (4) and the tension element (9) are connected as a composite assembly to the externally located control means (7) in such a way as to allow their rotation together as one.

4) An electrode catheter as in claim 1, wherein the second spiral wound wire (6) is accommodated slidably and coaxially within the first spiral wound wire (2), enveloped in a second sheath (6g) and anchored permanently to a worm (12) rigidly associated with the internal surface of the medial electrode (5), of which the thread is coupled with the first wire (2), such that an angular movement of the second wire (6) in either direction produces a distal or proximal translatory movement of the electrode along the operative portion (2a) of the first wire (2).

5) An electrode catheter as in claim 4, wherein the second spiral wound wire (6) terminates distally with an ogival head (13) of spherical profile seated coaxially in the distal end of the wire (6) and serving to favour sliding movement internally of the first spiral wound wire (2) whenever the configuration of the operative portion (2a) is altered.

6) An electrode catheter as in claim 1, wherein the operative portion (2a) of the first spiral wound wire (2) is fitted over a cylindrical shank (4c) afforded by the second ring (4), and secured by means of a fourth ring (20) crimped over the wire.

7) An electrode catheter as in claim 1, wherein

the movement of the first spiral wound wire (2), of the t nsion wire (9) and of the second spiral wound wire (6) is induced and controlled by means (7) incorporated into a single unit (14) operated from outside the body of the cardiac patient.

8) An electrode catheter as in claim 1, wherein the medial electrode (5) appears cylindrical in section and is embodied with flat external surfaces.

9) An electrode catheter as in claim 1, wherein the medial electrode (5) appears cylindrical in section and is embodied with spherical external surfaces.

10) An electrode catheter as in claim 1, wherein the second ring (4) is rendered electrically active in such a way as to function as a distal electrode.

11) An electrode catheter as in claim 1, wherein the first ring (3) is rendered electrically active in such a way as to function as a proximal electrode.

FIG1

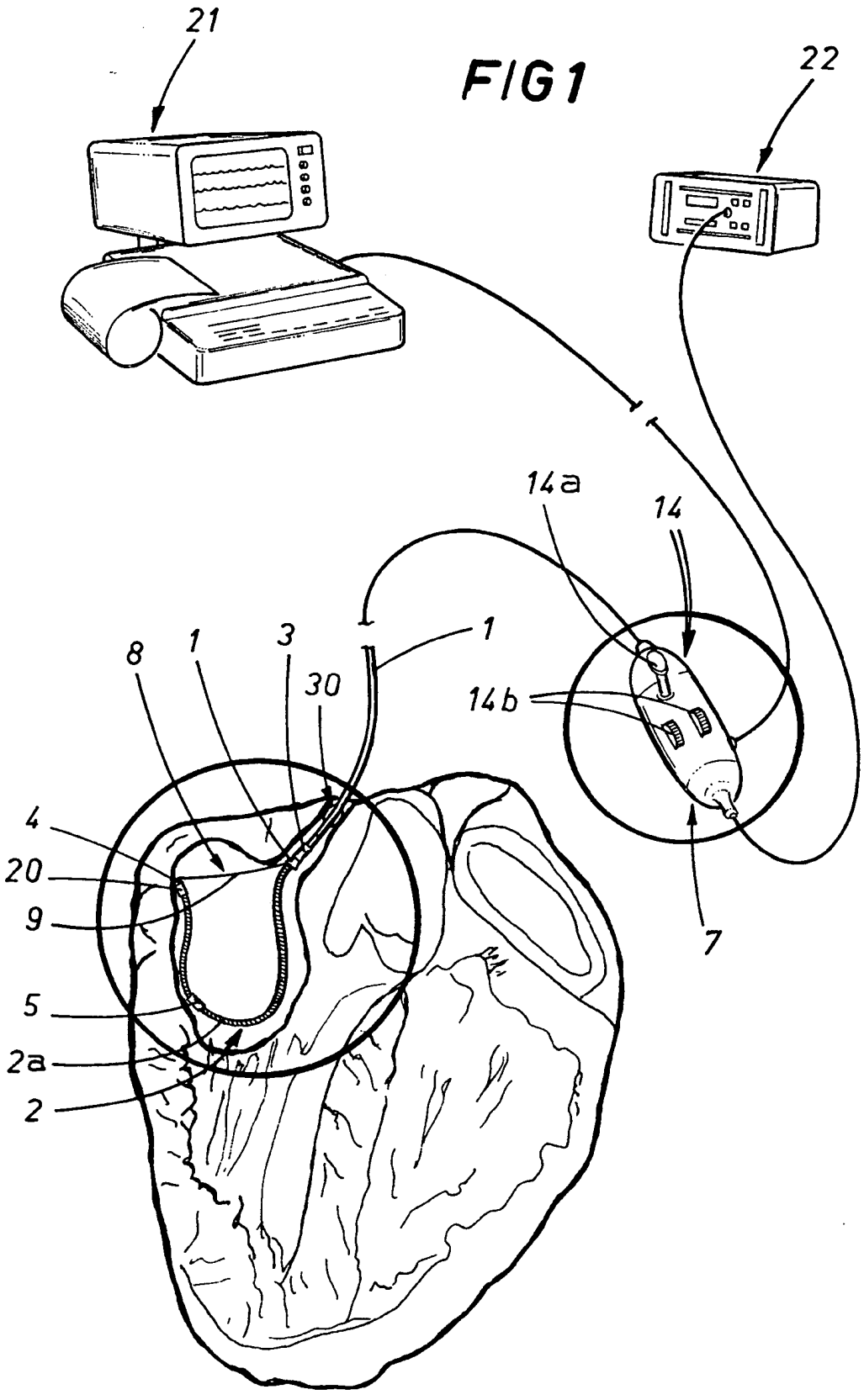
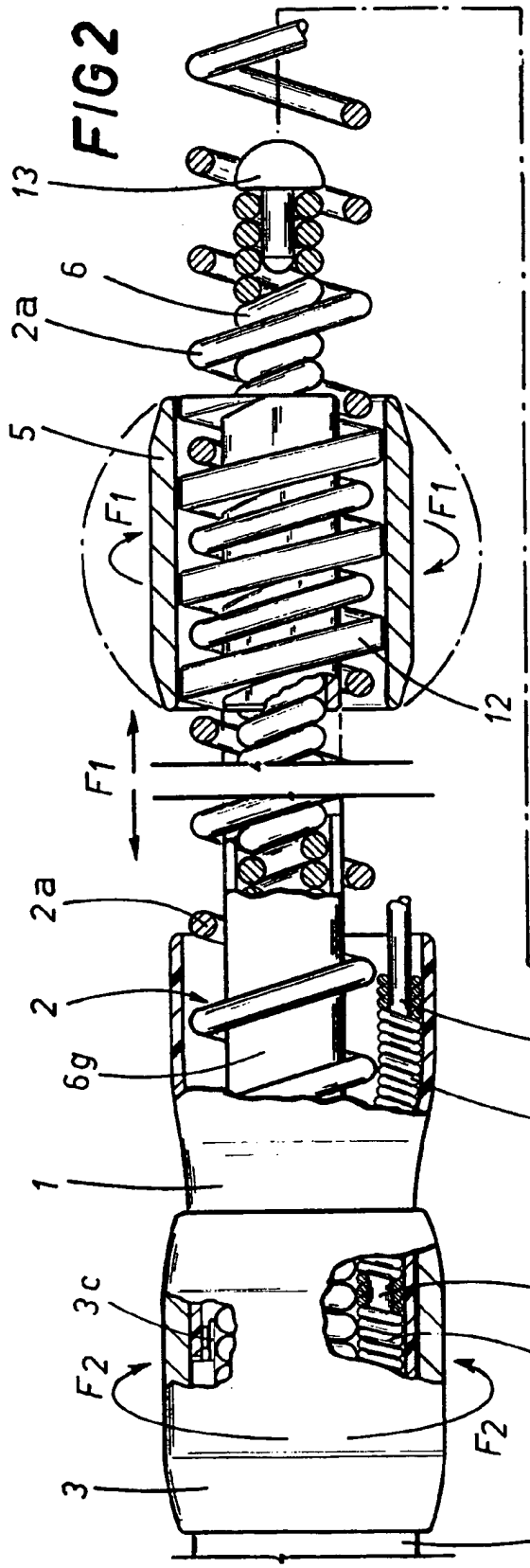


FIG2



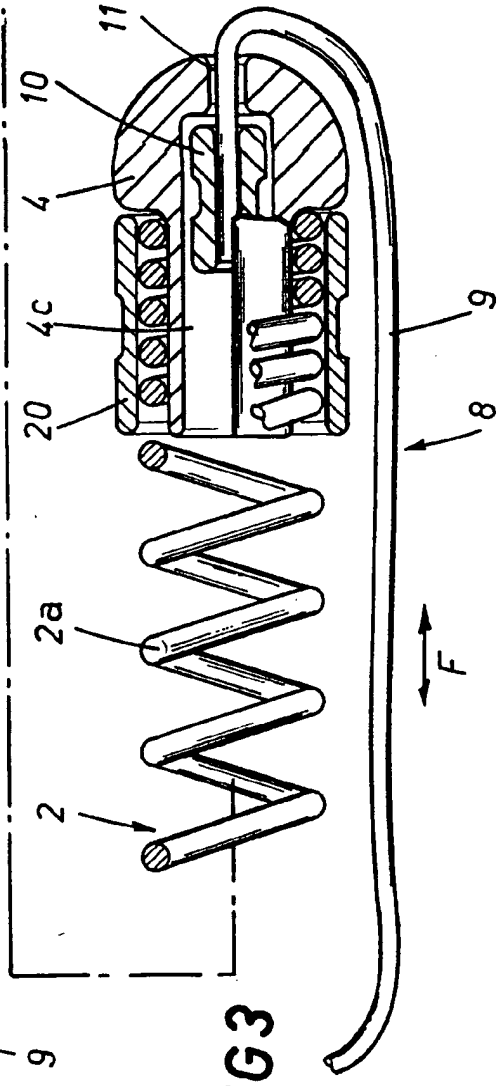


FIG3

FIG 4

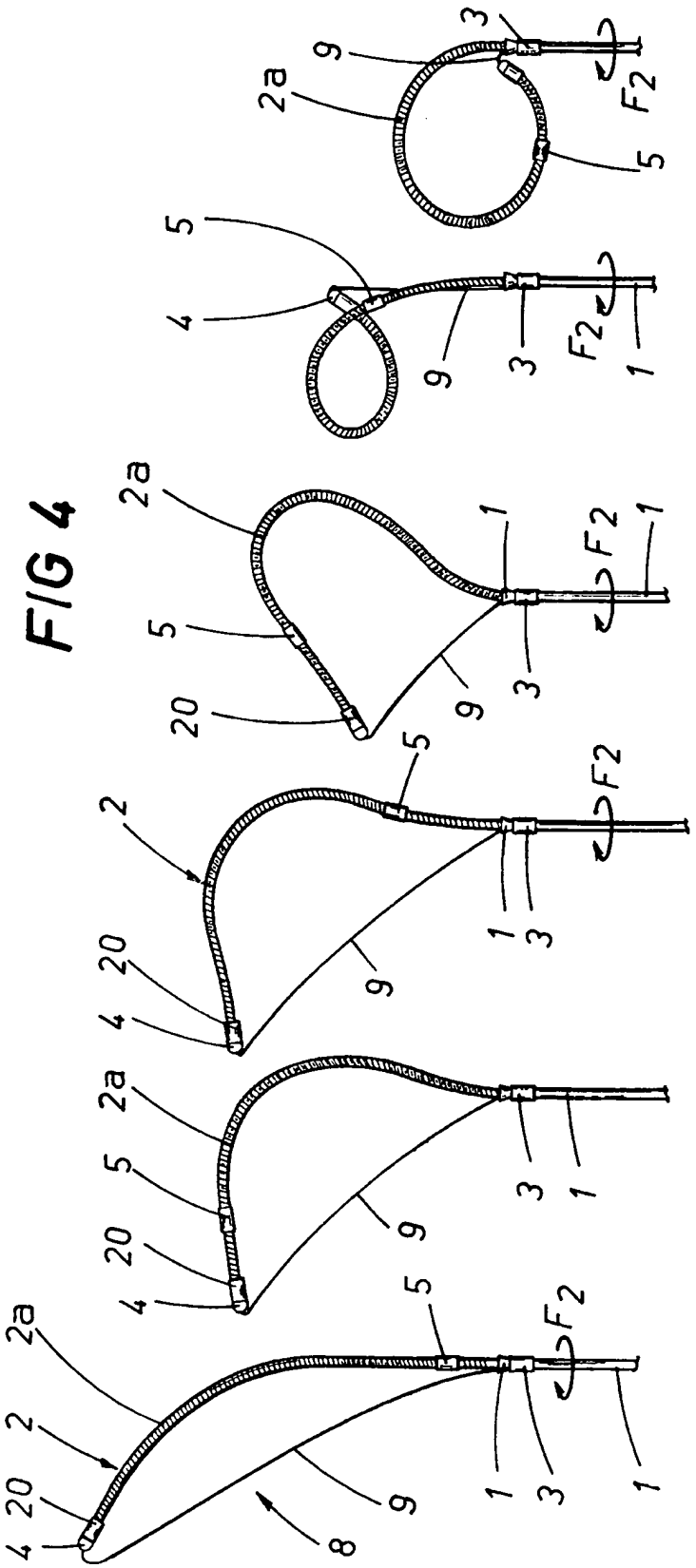


FIG 5

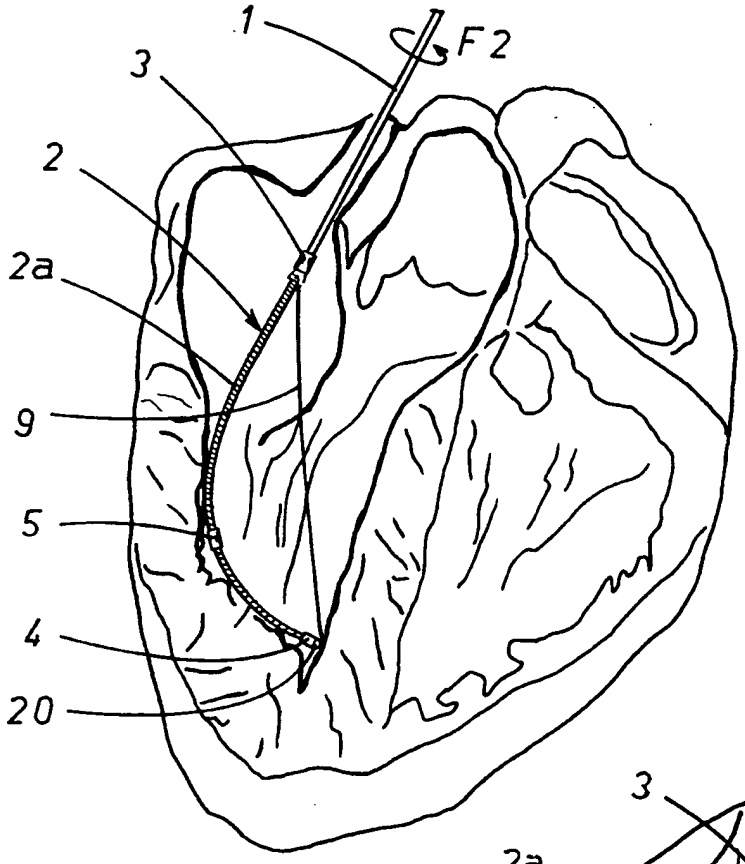


FIG 6

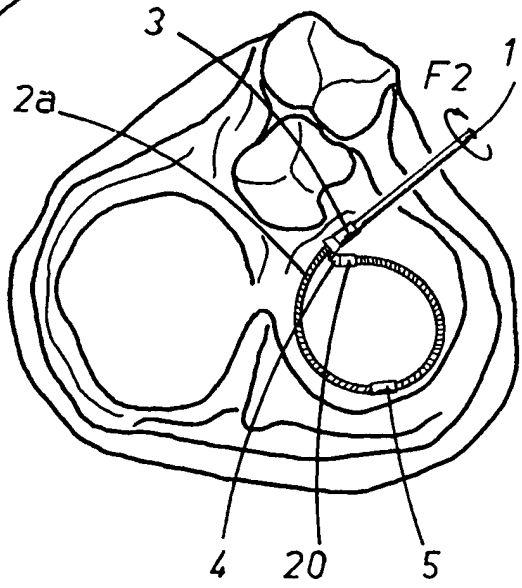
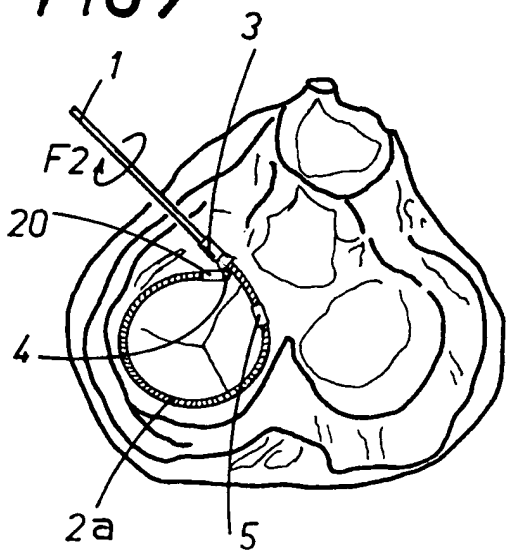


FIG 7



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EUROPEAN SEARCH REPORT

Application Number
EP 94 83 0007

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
A A	US-A-4 660 571 (S.R. HESS ET AL.) * column 4, line 32 - column 6, line 14 *	1,2 5,7,11	A61B5/042 A61B1/00
A	DE-A-28 00 362 (OLYMPUS OPTICAL CO., LTD.) * page 8, line 1 - line 11 * * page 9, line 27 - page 10, line 16 *	1,2	
A A	US-A-4 848 352 (P.J. POHNDORF ET AL.) * column 3, line 62 - column 5, line 17 *	1,5,8,10 11	
A A	US-A-4 969 463 (R.W. DAHL ET AL.) * column 6, line 14 - line 60 *	1,6,8,10 11	
A	US-A-4 757 827 (M. BUCHBINDER ET AL.) * column 4, line 29 - line 52 *	1,4	

TECHNICAL FIELDS SEARCHED (Int.Cl.5)

A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	17 May 1994	Rieb, K.D.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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